APPENDIX A: CDC GUIDANCE AND INFORMATION ON MICROORGANISMS

A.1 CDC Biosafety Level Criteria

The information in this appendix is taken from a Centers for Disease Control and Prevention (CDC) document which establishes the criteria for each Biosafety Level (BSL) of operation. This document, "Biosafety in Microbiological and Biomedical Laboratories" (CDC 1999), also known as the BMBL, presents the CDC and NIH recommendations and describes the combinations of standard and special microbiological practices, safety equipment, and facilities for Biosafety Level 1-4 laboratories. The BMBL "guidelines are now accepted as the international 'gold standard' for safely conducting microbiological research." (BMBL Dedication, CDC 1999)

References to page numbers and appendices are for that document. References to the laboratory director should be interpreted as meaning the manager of the proposed BSL-3 facility. The following is excerpted from Section III of the BMBL, pages 17 through 36. References made within the following text to appendices refer to the BMBL document, not to the appendices of the EA.

CDC 1999; Centers for Disease Control and Prevention, "Biosafety in Microbiological and Biomedical Laboratories," report by the Centers for Disease Control and Prevention and the National Institutes of Health, 4th Edition, Washington D.C. (April 1999).

Laboratory Biosafety Level Criteria

The essential elements of the four biosafety levels for activities involving infectious microorganisms and laboratory animals are summarized in Tables of this section and Section IV (see pages 52 and 75). The levels are designated in ascending order, by degree of protection provided to personnel, the environment, and the community.

Biosafety Level 1 (BSL-1)

Biosafety Level 1 is suitable for work involving well-characterized agents not known to consistently cause disease in healthy adult humans, and of minimal potential hazard to laboratory personnel and the environment. The laboratory is not necessarily separated from the general traffic patterns in the building. Work is generally conducted on open bench tops using standard microbiological practices. Special containment equipment or facility design is neither required nor generally used. Laboratory personnel have specific training in the procedures conducted in the laboratory and are supervised by a scientist with general training in microbiology or a related science.

The following standard and special practices, safety equipment and facilities apply to agents assigned to Biosafety Level 1:

A. *Standard Microbiological Practices*

1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments or work with cultures and specimens are in progress.

2. Persons wash their hands after they handle viable materials, after removing gloves, and before leaving the laboratory.

3. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for hum an use are not permitted in the work areas. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated and used for this purpose only.

4. Mouth pipetting is prohibited; mechanical pipetting devices are used.

5. Policies for the safe handling of sharps are instituted.

6. All procedures are performed carefully to minimize the creation of splashes or aerosols.

7. Work surfaces are decontaminated at least once a day and after any spill of viable material.

8. All cultures, stocks, and other regulated wastes are de-contaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are to be placed in a durable, leakproof container and closed for transport from the laboratory. Materials to be decontaminated outside of the immediate laboratory are pack-aged in accordance with applicable local, state, and federal regulations before removal from the facility.

9. A biohazard sign may be posted at the entrance to the laboratory whenever infectious agents are present. The sign may include the name of the agent(s) in use and the name and phone number of the investigator.

10. An insect and rodent control program is in effect (see Appendix G).

B. *Special Practices* None

C. *Safety Equipment (Primary Barriers)*

1. Special containment devices or equipment such as a biological safety cabinet are generally not required for manipulations of agents assigned to Biosafety Level 1.

2. It is recommended that laboratory coats, gowns, or uniforms be worn to prevent contamination or soiling of street clothes.

3. Gloves should be worn if the skin on the hands is broken or if a rash is present. Alternatives to powdered latex gloves should be available.

4. Protective eyewear should be worn for conduct of procedures in which splashes of microorganisms or other hazardous materials is anticipated.

D. *Laboratory Facilities (Secondary Barriers)*

1. Laboratories should have doors for access control.

2. Each laboratory contains a sink for hand washing.

3. The laboratory is designed so that it can be easily cleaned. Carpets and rugs in laboratories are not appropriate.

4. Bench tops are impervious to water and are resistant to moderate heat and the organic solvents, acids, alkalis, and chemicals used to decontaminate the work surface and equipment.

5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning.

6. If the laboratory has windows that open to the exterior, they are fitted with fly screens.

Biosafety Level 2 (BSL-2)

Biosafety Level 2 is similar to Biosafety Level 1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment. It differs from BSL-1 in that (1) laboratory personnel have specific training in handling pathogenic agents and are directed by competent scientists; (2) access to the laboratory is limited when work is being conducted; (3) extreme precautions are taken with contaminated sharp items; and (4) certain procedures in which infectious aerosols or splashes may be created are conducted in biological safety cabinets or other physical containment equipment.

The following standard and special practices, safety equipment, and facilities apply to agents assigned to Biosafety Level 2:

A. Standard Microbiological Practices

1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

2. Persons wash their hands after they handle viable materials, after removing gloves, and before leaving the laboratory.

3. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the work areas. Food is stored outside the work area in cabinets or refrigerators designated for this purpose only.

4. Mouth pipetting is prohibited; mechanical pipetting devices are used.

5. Policies for the safe handling of sharps are instituted.

6. All procedures are performed carefully to minimize the creation of splashes or aerosols.

7. Work surfaces are decontaminated on completion of work or at the end of the day and after any spill or splash of viable material with disinfectants that are effective against the agents of concern.

8. All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Materials to be decontaminated off-site from the facility are packaged in accordance with applicable local, state, and federal regulations, before removal from the facility.

9. An insect and rodent control program is in effect (see Appendix G).

B. Special Practices

1. Access to the laboratory is limited or restricted by the laboratory director when work with infectious agents is in progress. In general, persons who are at increased risk of acquiring infection, or for whom infection may have serious consequences, are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at increased risk of acquiring infections. The laboratory director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory or animal room.

2. The laboratory director establishes policies and procedures whereby only persons who have been advised of the potential hazards and meet specific entry requirements (e .g., immunization) may enter the laboratory.

3. A biohazard sign must be posted on the entrance to the laboratory when etiologic agents are in use. Appropriate information to be posted includes the agent(s) in use, the biosafety level, the required immunizations, the investigator's name and telephone number, any personal protective equipment that must be worn in the laboratory, and any procedures required for exiting the laboratory.

4. Laboratory personnel receive appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing).

5. When appropriate, considering the agent(s) handled, baseline serum samples for laboratory and other at-risk personnel are collected and stored. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the facility.

6. Biosafety procedures are incorporated into standard operating procedures or in a biosafety manual adopted or prepared specifically for the laboratory by the laboratory director. Personnel are advised of special hazards and are required to read and follow instructions on practices and procedures.

7. The laboratory director ensures that laboratory and support personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates or additional training as necessary for procedural or policy changes.

8. A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.

    a. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plastic ware should be substituted for glassware whenever possible.

    b. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for injection or aspiration of infectious materials. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.

    c. Syringes which re-sheathe the needle, needleless systems, and other safety devices are used when appropriate.

    d. Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and

broken glass are decontaminated before disposal, according to any local, state, or federal regulations.

9. Cultures, tissues, specimens of body fluids, or potentially infectious wastes are placed in a container with a cover that prevents leakage during collection, handling, processing, storage, transport, or shipping.

10. Laboratory equipment and work surfaces should be de-contaminated with an effective disinfectant on a routine basis, after work with infectious materials is finished, and especially after overt spills, splashes, or other contamination by infectious materials. Contaminated equipment must be decontaminated according to any local, state, or federal regulations before it is sent for repair or maintenance or pack aged for transport in accordance with applicable local, state, or federal regulations, before removal from the facility.

11. Spills and accidents that result in overt exposures to infectious materials are immediately reported to the laboratory director. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

12. Animals not involved in the work being performed are not permitted in the lab.

Safety Equipment (Primary Barriers)

1. Properly maintained biological safety cabinets, preferably Class II, or other appropriate personal protective equipment or physical containment devices are used whenever:

    a. Procedures with a potential for creating infectious aerosols or splashes are conducted. These may include centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers of infectious materials whose internal pressures may be different from ambient pressures, inoculating animals intranasally, and harvesting infected tissues from animals or embryonate eggs.

    b. High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory if sealed rotor heads or centrifuge safety cups are used, and if these rotors or safety cups are opened only in a biological safety cabinet.

2. Face protection (goggles, mask, face shield or other splatter guard) is used for anticipated splashes or sprays of infectious or other hazardous materials to the face when the microorganisms must be manipulated outside the BSC.

3. Protective laboratory coats, gowns, smocks, or uniforms designated for lab use are worn while in the laboratory. This protective clothing is removed and left in the laboratory before leaving for non-laboratory areas (e.g., cafeteria, library,

administrative offices). All protective clothing is either disposed of in the laboratory or laundered by the institution; it should never be taken home by personnel.

4. Gloves are worn when hands may contact potentially infectious materials, contaminated surfaces or equipment. Wearing two pairs of gloves may be appropriate. Gloves are disposed of when overtly contaminated, and removed when work with infectious materials is completed or when the integrity of the glove is compromised. Disposable gloves are not washed, reused, or used for touching "clean" surfaces (keyboards, telephones, etc.), and they should not be worn outside the lab. Alternatives to powdered latex gloves should be available. Hands are washed following removal of gloves.

D. *Laboratory Facilities* (Secondary Barriers)

1. Provide lockable doors for facilities that house restricted agents (as defined in 42 CFR 72.6).

2. Consider locating new laboratories away from public areas.

3. Each laboratory contains a sink for handwashing.

4. The laboratory is designed so that it can be easily cleaned. Carpets and rugs in laboratories are inappropriate.

5. Bench tops are impervious to water and are resistant to moderate heat and the organic solvents, acids, alkalis, and chemicals used to decontaminate the work surfaces and equipment.

6. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

7. Install biological safety cabinets in such a manner that fluctuations of the room supply and exhaust air do not cause the biological safety cabinets to operate outside their parameters for containment. Locate biological safety cabinets away from doors, from windows that can be opened, from heavily traveled laboratory areas, and from other potentially disruptive equipment so as to maintain the biological safety cabinets' air flow parameters for containment.

8. An eyewash station is readily available.

9. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

10. There are no specific ventilation requirements. However, planning of new facilities should consider mechanical ventilation systems that provide an inward flow of air without recirculation to spaces outside of the laboratory. If the laboratory has windows that open to the exterior, they are fitted with fly screens.

Biosafety Level 3 (BSL-3)

Biosafety Level 3 is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route. Laboratory personnel have specific training in handling pathogenic and potentially lethal agents, and are supervised by competent scientists who are experienced in working with these agents.

All procedures involving the manipulation of infectious materials are conducted within biological safety cabinets or other physical containment devices, or by personnel wearing appropriate personal protective clothing and equipment. The laboratory has special engineering and design features.

It is recognized, however, that some existing facilities may not have all the facility features recommended for Biosafety Level 3 (i.e., double-door access zone and sealed penetrations). In this circumstance, an acceptable level of safety for the conduct of routine procedures, (e.g., diagnostic procedures involving the propagation of an agent for identification, typing, susceptibility testing, etc.), may be achieved in a Biosafety Level 2 facility, providing 1) the exhaust air from the laboratory room is discharged to the outdoors, 2) the ventilation to the laboratory is balanced to provide directional airflow into the room, 3) access to the laboratory is restricted when work is in progress, and 4) the recommended Standard Microbiological Practices, Special Practices, and Safety Equipment for Biosafety Level 3 are rigorously followed. The decision to implement this modification of Biosafety Level 3 recommendations should be made only by the laboratory director.

The following standard and special safety practices, equipment and facilities apply to agents assigned to Biosafety Level 3:

A. *Standard Microbiological Practices*

1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

2. Persons wash their hands after handling infectious materials, after removing gloves, and when they leave the laboratory.

3. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear con tact lenses in laboratories should also wear goggles or a face shield. Food is stored out-side the work area in cabinets or refrigerators designated for this purpose only.

4. Mouth pipetting is prohibited; mechanical pipetting devices are used.

5. Policies for the safe handling of sharps are instituted.

6. All procedures are performed carefully to minimize the creation of aerosols.

7. Work surfaces are decontaminated at least once a day and after any spill of viable material.

8. All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method, such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Infectious waste from BSL-3 laboratories should be decontaminated before removal for off-site disposal.

9. An insect and rodent control program is in effect (see Appendix G).

B. *Special Practices*

1. Laboratory doors are kept closed when experiments are in progress.

2. The laboratory director controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. Persons who are at increased risk of acquiring infection or for whom infection may have serious consequences are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at risk of acquiring infections. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory. No minors should be allowed in the laboratory.

3. The laboratory director establishes policies and procedures whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements (e.g., immunization), and who comply with all entry and exit procedures, enter the laboratory or animal rooms.

4. When infectious materials or infected animals are present in the laboratory or containment module, a hazard warning sign, incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone number of the laboratory director or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.

5. Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing), and periodic testing as recommended for the agent being handled.

6. Baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel. Additional serum specimens may be periodically collected, depending on the agents handled or the function of the laboratory.

7. A biosafety manual specific to the laboratory is prepared or adopted by the laboratory director and biosafety precautions are incorporated into standard operating procedures. Personnel are advised of special hazards and are required to read and follow instructions on practices and procedures.

8. Laboratory and support personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates or additional training as necessary for procedural changes.

9. The laboratory director is responsible for ensuring that, before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory director or other competent scientist proficient in safe microbiological practices and techniques.

10. A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.

    a. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plastic-ware should be substituted for glassware whenever possible.

    b. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for injection or aspiration of infectious materials. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.

c. Syringes which re-sheathe the needle, needleless systems, and other safe devices are used when appropriate.

d. Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, and disposed of according to any local, state, or federal regulations.

11. All open manipulations involving infectious materials are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench. Clean-up is facilitated by using plastic-backed paper toweling on non-perforated work surfaces within biological safety cabinets.

12. Laboratory equipment and work surfaces should be decontaminated routinely with an effective disinfectant, after work with infectious materials is finished, and especially after overt spills, splashes, or other contamination with infectious materials.

    a. Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.

    b. Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local, state, or federal regulations.

13. Cultures, tissues, specimens of body fluids, or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

14. All potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories are decontaminated before disposal or reuse.

15. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained.

16. Animals and plants not related to the work being conducted are not permitted in the laboratory.

C. *Safety Equipment* (Primary Barriers)

1. Protective laboratory clothing such as solid-front or wrap-around gowns, scrub suits, or coveralls are worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overtly contaminated.

2. Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.

3. Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.

4. All manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonate eggs, etc., are conducted in a Class II or Class III biological safety cabinet (see Appendix A).

5. When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirators, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) are used.

6. Respiratory and face protection are used when in rooms containing infected animals.

D. *Laboratory Facilities* (Secondary Barriers)

1. The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable (see Appendix F). A clothes change room may be included in the passageway.

2. Each laboratory room contains a sink for handwashing. The sink is hands-free or automatically operated and is located near the room exit door.

3. The interior surfaces of walls, floors, and ceilings of areas where BSL-3 agents are handled are constructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip-resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

4. Bench tops are impervious to water and are resistant to moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.

5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

6. All windows in the laboratory are closed and sealed.

7. A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

8. Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavily-traveled laboratory areas.

9. A ducted exhaust air ventilation system is provided. This system creates directional airflow which draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

10. HEPA-filtered exhaust air from a Class II biologic al safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust air from Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets (see Appendix A).

11. Continuous flow centrifuges or other equipment that may produce aerosols are contained in devices that exhaust air through HEPA filters before discharge into the laboratory. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

12. Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

13. An eyewash station is readily available inside the laboratory.

14. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

15. The Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

16. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal, state, or local regulations.

A.2 CDC FACILITY REGISTRATION FOR TRANSFER OR RECEIPT OF SELECT AGENTS

The Regulation. Title 42 CFR Part 72.6 (Additional Requirements for Facilities Transferring or Receiving Select Agents) stems from the "Antiterrorism and Effective Death Penalty Act of 1996" (50 U.S.C. § 2301) which requires the Secretary of Health and Human Services to regulate the transfer of certain biological agents ("select agents") harmful to humans. The CDC is responsible to the Secretary for the management of the LR/SAT Program.

Background. *The Antiterrorism and Effective Death Penalty Act* of 1996, enacted on April 24, 1996, established new provisions to regulate transfer of hazardous agents and required HHS to issue rules to implement these provisions. The final rule was published in the Federal Register on October 24, 1996 and will become effective April 15, 1997. To comply with the final rule, commercial suppliers of select agents, as well as Government agencies, universities, research institutions, individuals, and private companies that transfer or obtain these agents, must register with the CDC. The rule also authorizes CDC to inspect those facilities seeking registration to determine whether the applicant facility meets the appropriate BSL requirements. In return for the certification and inspection, facilities are responsible for a site registration fee. This notice lays out those fees and provides technical clarification of related matters in the regulation.

Definitions. A facility is defined in 42 CFR 72.6(j) "as any individual or Government Agency, university, corporation, company, partnership, society, association, firm, or other legal entity located at a single geographic site that may transfer or receive through any means a select agent subject to this part." For the purpose of assessing the site registration fees, facilities are broken down into three categories, small, medium, and large, depending upon the size of the facility, the number of personnel working in the facility, and the amount of work done in the facility. A small facility has one laboratory area including a BSC and supporting supplies and equipment, or one room housing one or more animals (animal room) doing work with one select agent, or group of closely related select agents, at one BSL, by one principal investigator and his/her support staff. If the one laboratory area is used by more than one principal investigator or for more than one select agent or group of closely related select agents, the facility is a medium facility, which has laboratory areas and may have animal rooms that total between two and five rooms. All laboratories must be under the supervision of one responsible facility official and must be located in the same single geographic site. These laboratories shall be used by no more than five principal investigators and their support staffs, for work on no more than five select agents/groups of closely related select agents during the 3-year registration period. If more than five principal investigators work in the laboratories or more than five select agents (or groups of closely related select agents) are used, the facility is a large facility. A large facility has laboratory areas and may have animal rooms that total more than five rooms. All laboratories must be under the supervision of one responsible facility official and must be located in the same single geographic site. Any facility working with select agents at BSL-4, whether small, medium or large, is assessed an additional fee. In addition, any facility that makes more than 50 select agent transfers per year, whether small, medium or large, is assessed an additional fee.

ADDITIONAL INFORMATION AND CLARIFICATION FROM CDC (www.cdc.gov/od/0hs/irsat/addinfo.htm)

Overview: CDC has published regulations regarding access, use and transfer of select agents for research purposes. These regulations are designed to ensure these infectious agents and toxins are shipped only to institutions or individuals equipped to handle them appropriately and only to those who have legitimate reasons to use them, as well as to implement a system whereby scientists and researchers involved in legitimate research may continue transferring and receiving these agents without undue burdens.

The regulation includes six components:

1. A list of biological agents ("select agents") that have the potential to pose a severe threat to public health and safety. This list includes approximately 40 viruses, bacteria, rickettsia, fungi, and toxins whose transfer in the United States is controlled due to their capacity for causing substantial harm to human health.

2. Registration of facilities transferring these agents. Organizations that transfer or obtain these agents must register with the Secretary of HHS by providing sufficient information that the facility meets BSL requirements for working with the particular biological agent. Registered facilities will be issued a unique registration number to be used to validate all requests for transfer of these agents.

3. Process to document successful transfer of agents. The regulation requires both the shipping and receiving parties to complete an approved transfer form, which includes information on both parties, the agent being transferred, and the proposed use of the agent.

4. Verification procedures, including audit, quality control, and accountability mechanisms. Each facility shipping or receiving a select agent must have a "responsible facility official." This official must sign each request, certifying that the requestor of the agent is officially affiliated with the facility and that the laboratory meets guidelines for working with the requested agent. The "responsible facility official" sending the agent is required to verify that the receiving facility holds a currently valid registration number.

5. Agent disposal requirements. Facilities must have procedures in place for the appropriate disposal of select agents.

6. Research and clinical exemptions. Certain vaccine strains of select agents are exempt from the list of selected infectious agents. Transfer of clinical specimens for diagnostic, reference, or verification purposes is also exempt. Certain toxins, if used for research purposes, are exempt. Clinical laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, which utilize these select agents for diagnostic, reference, verification or proficiency testing purposes, are exempt.

FACILITY REGISTRATION - SECONDARY SITES

Under the following conditions a secondary site could be covered under a single registration:

- The Responsible Facility Official is the same person at both facilities and would be available.
- The secondary facility meets the requirements set forth in 72.6 section "(j) Definitions" Facility", "... located at a single geographic site..." (e.g. same mailing address).
- Only personnel from the facility transport the select agent between the primary and secondary site.

If these conditions cannot be met, than the secondary site would have to register separately.

DESIGNATION OF AN ALTERNATE "RESPONSIBLE FACILITY OFFICIAL"

For the purposes of this regulation, the CDC recognizes a single person as the responsible facility official. The CDC realizes that this may not be practical in certain cases. As such, the CDC recommends that the responsible facility official designate one or more alternates and provide to the CDCs office those names in case there would be a need to verify an EA-101, the CDC would have the designated alternates on file. The designated alternate responsible facility official must also meet the requirements set forth in section "(j) Definitions" for "Responsible facility official" as follows:

"Responsible facility official means an official authorized to transfer and receive select agents covered by this part on behalf of the transferor's and/or requestor's facility. This person should be either a safety officer, a senior management official of the facility, or both. The responsible facility official should not be an individual who actually transfers or receives an agent at the facility."

ATTENUATED STRAINS AND REQUESTS FOR EXEMPTIONS

The following statement is from the preamble of 42 CFR 72.6: *"CDC has determined that it is premature to issue blanket exemptions of attenuated, avirulent, or less pathogenic strains of agents on the restricted list at this time. Attenuated strains of select agents approved for human vaccination purposes by FDA or other recognized national or international organizations will be exempt. All other attenuated, avirulent, or less pathogenic strains will not be exempt at this time."*

The CDC interprets this to apply to veterinary vaccination purposes as well. Therefore, if the attenuated strain of the select agent that LLNL would be working with has been approved by FDA or USDA for vaccination purposes, or has received an Investigational New Drug license with supporting documentation of safety in humans, then the CDC would consider this strain to

be exempt from this regulation. If the strain of the select agent LLNL would be working with does not meet the above criteria, then it would still considered a select agent and would not be exempt from the regulation. In this case, LLNL may apply for an exemption as described in Appendix A of Part 72.6, under the section "Additional Exemptions." Individuals seeking such an exemption should submit a request to CDC that specifies the agent or strain to be exempted and explains why such an exemption should be granted. A committee of experts would be convened to review the merits of the request. The proposed exemption would be published in the Federal Register to inform the public and solicit comment. Pending the completion of this process and its outcome, use of the agent must be in compliance with 42 CFR Part 72.6.

A.3: BACKGROUND INFORMATION ON UNDERSTANDING INFECTIOUS MICROORGANISMS AND THE LLNL PROPOSED ACTION MICROORGANISMS

Terminology and Lists of Microorganisms

There are a number of terms used in this document that pertain to infectious microorganisms and these are defined in either footnotes as they are presented in the text. These include, biological agents, select agents, etiologic agents, biological warfare agents, and infectious agents. The terminology is often dependant upon the Federal Agency using the term and the Government regulation. For example, "select agent" is a CDC term defined as "a microorganism (virus, bacterium, rickettsia) or toxin…including genetically modified organisms" that can be found in Appendix A of 42 CFR 72. That CFR, however, is titled *Interstate Shipment of Etiologic Agents* and has another table in it (Table 72.3) listing "etiologic agents" as a "viable microorganism or its toxin which causes, or may cause, human disease." There are additional infectious microorganism lists or rankings that are proposed for codification (e.g., 49 CFR 171-178).

Risk Associated with Infectious Agents

A literature search identified three sources of information ranking infectious agents by risk category. These are from the CDC (CDC 2000a), the NIH (NIH 2001), and a summary compendium that includes an earlier version of the NIH ranking from the American Biological Safety Association (ABSA) (ABSA 1998). The microorganism list from the ABSA summary was used as a starting point for creating the tables at the end of Appendix A. The literature search found this listing as the most complete and available from a reliable source. It does not contain all the microorganisms discussed or listed in the CDC BMBL (CDC 1999), nor does the BMBL refer to all the microorganisms listed in the ABSA list. Therefore, those preparing risk assessments should refer to both documents for relevant information. However, as a compendium of possible infectious organisms that might be handled in a microbiological laboratory, it is more than adequate. The tables at the end of Appendix A include some additional microorganisms from the newest CDC (2000a) and NIH (2001) sources. The following subsections briefly describe the three information sources.

CDC 2000 Ranking. The CDC ranking was described in the Johns Hopkins University's *Biodefense Quarterly* (JH 1999), as follows: "On June 3-4, 1999, the Centers for Disease Control and Prevention (CDC) convened a panel of experts in medicine and public health, military intelligence and law enforcement, and security for the purpose of identifying biological agents considered to be of greatest potential concern." The outgrowth of this meeting and subsequent interagency discussion resulted in a CDC *Morbidity and Mortality Weekly Report* (MMWR) that presented the panels recommendations for "critical biological agents" (CDC 2000a). The mandate of this panel was to identify the critical biological agents associated with bioterrorism, the resulting analysis focused on the relative risk between infectious agents that might be of concern.

The CDC segregated the list of agents they deemed most problematic into three categories. Category A included organisms that pose the highest risk. These can be easily disseminated or

transmitted person-to-person, cause high mortality (i.e., death) with potential for major public health impact, and require special action for public health preparedness. Category A includes:

- *Variola major* (smallpox)
- *Bacillus anthracis* (anthrax)
- *Yersinia pestis* (plague)
- *Clostridium botulinum* toxin (botulism)
- *Francisella tularensis* (tularaemia)
- filoviruses (Ebola hemorrhagic fever and Marburg fever)
- arenaviruses (Lassa fever, and Junin or Argentine hemorrhagic fever and related viruses)

The second category, Category B, includes microorganisms that are moderately easy to disseminate, have moderate morbidity (i.e., ability to cause disease) and low mortality, but require enhanced disease surveillance. Category B includes:

- *Coxiella burnetti (*Q fever)
- *Brucella spp*. (brucellosis)
- *Burkholderia mallei (*glanders)
- alphaviruses (Venezuelan encephalomyelitis and eastern and western equine encephalomyelitis)
- ricin toxin
- epsilon toxin (from *Clostridium perfringens*)
- *Staphylococcus* enterotoxin B

A subset of Category B includes the food- and water-borne pathogens:

- *Salmonella* species
- *Shigella dysenteriae*
- *Escherichia coli* O 157:H7
- *Vibrio cholerae*
- *Cryptosporidium parvum*

The last and lowest risk category, Category C, includes emerging pathogens that could be engineered for mass dissemination because of availability, ease of production and dissemination, and the potential for high morbidity and mortality and consequent major health impact. These include:

- Nipah virus
- hantaviruses
- tick-borne hemorrhagic fever viruses
- tick-borne encephalitis viruses
- yellow fever
- multi-drug resistant tuberculosis

The NIH 2001 Ranking. The risk group ranking provided by NIH "is based on the potential effect of a biological agent on a healthy human adult and does not account for instances in which an individual may have increased susceptibility to such agents, e.g., pre-existing diseases, medications, compromised immunity, pregnancy or breast feeding (which may increase exposure of infants to some agents)." This ranking is known as the *Classification of Human Etiologic Agents on the Basis of Hazard* and is included in Appendix B of the *NIH Guidelines: Recombinant DNA and Gene Transfer; Guidelines for Research Involving Recombinant DNA Molecules* (NIH 2001). Agents are classified into four risk groups (RG):

- RG1 includes agents that are not associated with disease in health human adults
- RG2 includes agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are *often* available
- RG3 includes agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions *may* be available
- RG4 includes agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are *not usually* available

The ABSA 1998 Ranking Table. The ABSA "Risk Group Classification for Infectious Agents" (ABSA 1998) was developed on the basis of relative risk. The factors that were taken into consideration were the: pathogenicity of the organism, mode of transmission and host range, availability of effective preventive measures (for example, vaccines), availability of effective treatment (such as antibiotics), and other factors.

The intent of the ranking table is to provide risk information for the research community as part of their biosafety risk assessments. The ABSA tables include four risk-group spreadsheets prepared in Adobe™ portable document format (pdf) that are downloadable from the world-wide-web (http://www.absa.org/riskgroups/). These tables provide information on infectious bacteria, viruses, fungi, and parasites (ABSA 1998). The bacteria table includes Rickettsia, and the virus table includes prions. The ranking information associated with listed microorganisms on these tables reflect the combined sources of information from the European Economic Community directives, the NIH Guidelines on Recombinant DNA, the Canadian Laboratory Biosafety Guidelines, and the CDCs BMBL. These tables are not included their entirety in this EA due to their large size.

LLNL Proposed Action Microorganisms. LLNL envisions that the proposed laboratory facility could handle any of the bacterial or viral infectious agents listed in the BSL-3 category by CDC in Section VII of the BMBL (CDC 1999) or future editions and revisions of that guidance. In addition, the proposed laboratories could handle other bacterial or viral infectious organisms not specifically or currently regulated by CDC or other Federal agencies such as those shown in the tables at the end of Appendix A. Only by prior approval of the LLNL Institutional Biosafety Committee (IBC), and after a risk analysis is conducted, would any infectious agent be considered for use in the proposed laboratories. Current plans are for these laboratories to handle live microorganisms or their DNA, RNA[1], proteins[2], or attenuated organisms[3] in their vegetative forms[4].

[1] RNA or ribonucleic acid is similar and complementary to DNA in that it transcribes the encoded chromosomal information to create proteins. In certain viruses they take the place of DNA.

LLNL has an immediate interest in any organism or toxin identified as a "select agent" by the CDC. Also of interest are Dengue virus, West Nile fever virus, and Wheat rust (*Tilletia spp*. fungi). The tables at the end of this appendix include all of the select agents and many additional microorganisms.

These microorganisms could be processed a number of ways, for example:

- Selective culturing[5]
- Sample amplification[6]
- Chemical separation of parts (e.g., DNA, RNA, protein expression)
- Centrifugation[7]
- Freezing
- Decontamination by autoclaving[8]
- Decontamination by chemical disinfection

[2] Proteins are building blocks of cells and are used for support, storage, transport of substances, and defense against invaders.
[3] Attenuatedorganisms that have been deactivated by various means so that they have very limited growth potential or pathogenicity.
[4] A vegetative form is one that is capable of actively growing.
[5] Selective culturing uses nutrients and environmental controls to enhance the growth of some microorganisms relative to others which might also be present.
[6] Amplification is the process to rapidly and significantly increase the number of microorganisms in a sample.
[7] Centrifugation is the process of spinning a sample at a high rate of revolution to cause a separation of materials based upon their density.
[8] Autoclaving is the process of using steam under pressure for a sufficient time to produce sterilization of materials.

Table A-1. Bacterial Microorganisms and Their Safety Classification

Genus[1]	Species[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
Acinetobacter	*spp.*				
Acinetobacter	*baumannii*				2
Acinetobacter	*lwoffi*				
Actinobacillus	*actinomycetem-comiana*				2 implied
Actinobacillus	*spp.*				2
Actinomadura	*madurae*				
Actinomadura	*pelletieri*				
Actinomyces	*bovis*				
Actinomyces	*gerencseriae*				
Actinomyces	*israelii*				
Actinomyces	*naeslundii*				
Actinomyces	*pyogenes*				2
Actinomyces	*spp.*				
Aeromonas	*hydrophilia*				2
Aeromonas	*punctata*				
Aeromonas	*spp.*				
Afpia	*spp.*				
Amycolata	*autotrophica*				2
Arachnia	*propionica*				
Arcanobacterium	*haemolyticum*				2
Archanobacterium	*equi*				
Arizona	*hinshawii*				2
Bacillus	*anthracis*	✸	2/3 (I/E)	A	2
Bacillus	*cereus*				
Bacillus	*subtilis*				1
Bacillus	*licheniformis*				1
Bacillus	*thuringiensis*				
Bacteroides	*fragilis*				
Bacteroides	*spp.*				
Bartonella	*bacilliformis*				3 implied
Bartonella	*elizabethae*				3 implied
Bartonella	*spp.*				3

[1] Basic genus and specie list is from ABSA 1998 with some additions.
[2] Select agent list is from 42 CFR 72
[3] Biosafety Level is from CDC 1999 - all organisms shown require import or transfer permit from CDC
[4] Risk Grouping from CDC 2000a
[5] NIH Risk Groups (RG) are from NIH 2001
RG 1 not associated with disease in healthy human adults
RG 2 associated with human disease that is rarely serious and prophylactic intervention ***often*** available
RG 3 associated with human disease that is serious or lethal and prophylactic intervention ***may be*** available
RG 4 associated with human disease that is serious or lethal and prophylactic intervention ***not usually*** available
I/E Requires import and/or export permit from CDC and/or Deparment of Commerce or I/E
AP - animal pathogen
* activities with high droplet or aerosol production potential
✸ applicable organism

Table A-1. Bacterial Microorganisms and Their Safety Classification

Genus[1]	Species[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
Bartonella	*henselae*				2
Bartonella	*quintana*				2
Bartonella	*vinsonii*				2
Bordetella	*spp.*				2
Bordetella	*bronchiseptica*				2 implied
Bordetella	*parapertussis*				2 implied
Bordetella	*pertussis*		2		2
Borrelia	*burgdorferi*				2
Borrelia	*duttoni*				
Borrelia	*recurrentis*				2
Borrelia	*spp.*				
Borrelia	*vincenti*				
Brucella	*abortus*	✸	3 (I/E)	B	3
Brucella	*canis*	✸	3 (I/E)	B	3
Brucella	*melitensis*	✸	3 (I/E)	B	3
Brucella	*ovis*			B	3 implied
Brucella	*spp.* (except *B. ovis*)		3 (I/E)	B	3
Brucella	*suis*	✸	3 (I/E)	B	3
Burkholderia	*spp.*				
Burkholderia	*mallei*	✸	2/3* implied (I/E)	B	3
Burkholderia	*pseudomallei*	✸	2/3* (I/E)		3
Calymmatobacterium	*granulomatis*				
Campylobacter	*coli*		2		2
Campylobacter	*fetus* (*ssp. fetus*)		2		2
Campylobacter	*jejuni*		2		2
Campylobacter	*laridis*				
Campylobacter	*spp.*		2 implied		
Campylobacter	*sputorum*				
Capnocytophaga	*spp.*				
Cardiobacterum	*hominis*				
Chlamydia	*pneumoniae*		2/3*		2
Chlamydia	*psittaci*		2/3*		2

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Chlamydia	*spp.* (*C. pneumoniae*)		2/3* implied		3
Chlamydia	*trachomatis*		2/3*		2
Citrobacter	*spp.*				
Clostridium	*botulinum*	✸	2/3*	A	2
Clostridium	*chauvoei*				2
Clostridium	*difficile*				
Clostridium	*equi*				
Clostridium	*haemolyticum*				2
Clostridium	*histolyticum*				2
Clostridium	*novyi*				2
Clostridium	*perfringens*			B	
Clostridium	*septicum*				2
Clostridium	*sordelli*				
Clostridium	*spp.*				
Clostridium	*tetani*		2		2
Corynebacterium	*bovis*				
Corynebacterium	*diphtheriae*		2		2
Corynebacterium	*matruchotii*				
Corynebacterium	*minutissimum*				
Corynebacterium	*pseudotuberculosis*				2
Corynebacterium	*renale*				2
Corynebacterium	*spp.*				
Corynebacterium	*ulcerans*				
Coxiella	*burnetii*	✸	3 (I/E)	B	3
Dermatophilus	*congolensis*				2
Edwardsiella	*tarda*				2
Eikenella	*corrodens*				
Enterobacter	*aerogenes/cloacae*				
Enterobacter	*spp.*				
Enterococcus	*spp.*				
Erlichia	*sennetsu*				
Erlichia	*spp.*				
Erysipelothrix	*rhusiopathiae*				2

[1] Basic genus and specie list is from ABSA 1998 with some additions.
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[3] Biosafety Level is from CDC 1999 - all organisms shown require import or transfer permit from CDC
[4] Risk Grouping from CDC 2000a
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Erysipelothrix	*spp.*				
Escherichia	*coli* (pathogenic strains)		2	B	2
Escherichia	*coli K12* (genetically crippled)				1
Flavobacterium	*meningosepticum*				
Flavobacterium	*spp.*				
Fluoribacter	*bozemanae*				
Francisella	*novocida*				
Francisella	*tularensis* (Type A)	✸	2/3	A	3
Francisella	*tularensis* (Type B)	✸	2/3	A	3
Fusobacterium	*necrophorum*				
Fusobacterium	*spp.*				
Gardnerella	*vaginalis*				
Haemophilus	*ducreyi*				2
Haemophilus	*influenzae*				2
Haemophilus	*spp.*				
Hartmanella	*spp.*				
Helicobacter	*pylori*		2		2
Herellea	*vaginicola*				
Kingella	*kingae*				
Klebsiella	*oxytoca*				1
Klebsiella	*pneumoniae*				2
Klebsiella	*spp.*				2
Lactobacillus	*spp.*				
Legionella	*pneumophila*		2/3*		2
Legionella	*spp.*		2/3*		2
Legionella	*like organisms*		2/3*		
Leptospira	*interrogans*		2 (I/E)		2
Listeria	*ivanovii*		2 implied (I/E)		2 implied
Listeria	*monocytogenes*		2 (I/E)		2 implied
Listeria	*spp.*		2 implied (I/E)		2
Mima	*polymorpha*				
Moraxella	*spp.*				2
Morganella	*morganii*				

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[2] Select agent list is from 42 CFR 72
[3] Biosafety Level is from CDC 1999 - all organisms shown require import or transfer permit from CDC
[4] Risk Grouping from CDC 2000a
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Mycobacterium	*africanum*			C	2 implied
Mycobacterium	*asiaticum*		2		2
Mycobacterium	*avium-intracelluare*		2		2
Mycobacterium	*bovis*		2/3 (I/E)	C	3
Mycobacterium	*chelonei*		2		2
Mycobacterium	*fortuitum*		2		2
Mycobacterium	*kansasii*		2		2
Mycobacterium	*leprae*		2		2
Mycobacterium	*malmoense*		2		2
Mycobacterium	*marinum*		2		2
Mycobacterium	*microti*				2 implied
Mycobacterium	*paratuberculosis*		2		2
Mycobacterium	*scrofulaceum*		2		2
Mycobacterium	*simiae*		2		2
Mycobacterium	*spp.* (except *M. tuberculosis* complex)		2		
Mycobacterium	*szulgai*		2		2
Mycobacterium	*tuberculosis*		3	C	3
Mycobacterium	*ulcerans*		2		2
Mycobacterium	*xenopi*		2		2
Mycoplasma	*hominis*				2 implied
Mycoplasma	*mycoides*				Restricted AP
Mycoplasma	*pneumoniae*				2 implied
Mycoplasma	*agalactiae*				Restricted AP
Mycoplasma	*spp. (except M. mycoides & M. agalactiae)*				2
Neisseria	*gonorrhoeae*		2/3*		2
Neisseria	*meningitidis*		2/3*		2
Neisseria	*spp.*		2/3* implied		
Nocardia	*asteroides*				2
Nocardia	*brasiliensis*				2
Nocardia	*caviae*				

[1] Basic genus and specie list is from ABSA 1998 with some additions.
[2] Select agent list is from 42 CFR 72
[3] Biosafety Level is from CDC 1999 - all organisms shown require import or transfer permit from CDC
[4] Risk Grouping from CDC 2000a
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Genus[1]	Species[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
Nocardia	*farcinica*				
Nocardia	*nova*				
Nocardia	*spp.*				
Nocardia	*transvalensis*				2
Nocarida	*otitidis-caviarum*				2
Pasteurella	*haemolytica*				
Pasteurella	*multocida*				3
Pasteurella	*pneumotropica*				
Pasteurella	*spp. (virulent strains)*				3
Peptostreptococcus	*anaerobius*				
Plesiomonas	*shigelloides*				
Porphyromonas	*spp.*				
Prevotella	*spp.*				
Proteus	*mirabilis*				
Proteus	*penneri*				
Proteus	*spp.*				
Proteus	*vulgaris*				
Providencia	*alcalifaciens*				
Providencia	*rettgeri*				
Providencia	*spp.*				
Pseudomonas	*aeruginosa*				
Pseudomonas	*spp.*				
Rhodococcus	*equi*				2
Rickettsia	*(vole)*				
Rickettsia	*akari*		2/3 (I/E)		3
Rickettsia	*australis*		2/3 (I/E)		3
Rickettsia	*canada*				3
Rickettsia	*conorii*		2/3 (I/E)		3
Rickettsia	*japonicum*		2/3 (I/E)		
Rickettsia	*montana*				
Rickettsia	*mooseri*		2/3 (I/E)		3
Rickettsia	*parkeri*				
Rickettsia	*prowazekii*	✸	2/3 (I/E)		3

[1] Basic genus and specie list is from ABSA 1998 with some additions.
[2] Select agent list is from 42 CFR 72
[3] Biosafety Level is from CDC 1999 - all organisms shown require import or transfer permit from CDC
[4] Risk Grouping from CDC 2000a
[5] NIH Risk Groups (RG) are from NIH 2001
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Genus[1]	Species[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
Rickettsia	*rhipicephali*				
Rickettsia	*rickettsii*	✸	2/3 (I/E)		3
Rickettsia	*sennetsu*				
Rickettsia	*sibirica*		2/3 (I/E)		3
Rickettsia	*spp.*				
Rickettsia	*tsutsugamushi*		2/3 (I/E)		3
Rickettsia	*typhi (mooseri)*		2/3 (I/E)		3
Salmonella	*arizonae*		2	B	2
Salmonella	*cholerasuis*		2	B	2
Salmonella	*enteritidis*		2	B	2
Salmonella	*gallinarum-pullorum*		2	B	2
Salmonella	*meleagridis*		2	B	2
Salmonella	*paratyphi* (Type A, B, C)		2	B	2
Salmonella	*spp.*		2	B	2 implied
Salmonella	*typhi*		2/3* (I/E)	B	2
Salmonella	*typhimurium*		2	B	2
Serpulina	*spp.*				
Serratia	*marcescens*				
Serretia	*liquefaciens*				
Shigella	*boydii*		2 (I/E) implied		2
Shigella	*dysenteriae* (Type 1)		2 (I/E) implied	B	2
Shigella	*flexneri*		2 (I/E)		2
Shigella	*sonnei*		2 (I/E) implied		2
Shigella	*spp.*		2 (I/E)		2 implied
Sphaerophorus	*necrophorus*				2
Staphylococcus	*aureus*			B	2
Staphylococcus	*epidermidis*			B	
Streptobacillus	*moniliformis*				2
Streptobacillus	*spp.*				
Streptococcus	*agalactiae*				2 implied
Streptococcus	*pneumoniae*				2
Streptococcus	*pyogenes*				2
Streptococcus	*spp.*				2

[1] Basic genus and specie list is from ABSA 1998 with some additions.
[2] Select agent list is from 42 CFR 72
[3] Biosafety Level is from CDC 1999 - all organisms shown require import or transfer permit from CDC
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RG 4 associated with human disease that is serious or lethal and prophylactic intervention ***not usually*** available
I/E Requires import and/or export permit from CDC and/or Deparment of Commerce or I/E
AP - animal pathogen
* activities with high droplet or aerosol production potential
✸ applicable organism

Table A-1. Bacterial Microorganisms and Their Safety Classification

Genus[1]	Species[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
Streptococcus	*suis*				
Treponema	*carateum*				2
Treponema	*pallidum*		2		2
Treponema	*pertenue*				
Treponema	*spp.*				
Treponema	*vincentii*				
Ureaplasma	*urealyticum*				
Vibrio	*cholerae*		2 (I/E)	B	2
Vibrio	*parahaemolyticus*		2 (I/E)		2
Vibrio	*spp.*		2 (I/E) implied		2 implied
Vibrio	*vulnificus*				2
Yersinia	*enterocolitica*				2
Yersinia	*pestis*	✸	2/3* (I/E)	A	3
Yersinia	*pseudotuberculosis*				
Yersinia	*spp.* (except *Y. pestis*)				

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[4] Risk Grouping from CDC 2000a
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AP - animal pathogen
* activities with high droplet or aerosol production potential
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Table A-2. Viral Microorganisms and Their Safety Classifications

Viral Group[1]	Name[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
Adenoviridae	Adenovirus (human, all types)				2
Arenaviruses	Flexal	✸			3
Arenaviruses	Guanarito	✸	4 (E)	A	4
Arenaviruses	Junin virus	✸	V2 (E), 3/4 (E)	A	V3, 4
Arenaviruses	Lassa fever virus	✸	4 (E)	A	4
Arenaviruses	Lymphocytic choriomeningitis (neurotropic virus)		2/3* (E)	A	3
Arenaviruses	Lymphocytic choriomeningitis (non-neurotropic virus)		2/3* (E)		2
Arenaviruses	Machupo virus	✸	4 (E)	A	4
Arenaviruses	Mopeia virus (and other Tacaribe viruses)		3		BMBL
Arenaviruses	Sabia	✸	4 (E)	A	4
Arenaviruses	Tacaribe complex		2		2
Astroviridae	Astroviridae				
Bunyaviridae	Bunyaviridae (others known to be pathogenic)				
Bunyaviridae/ Bunyavirus Group	Bunyamwera virus		2		2
Bunyaviridae/ Bunyavirus Group	Bunyavirus				
Bunyaviridae/ Bunyavirus Group	California encephalitis virus		2		BMBL
Bunyaviridae/ Bunyavirus Group	Oropouche virus		3		BMBL
Bunyaviridae/ Bunyavirus Group	Tensaw virus		2		BMBL
Bunyaviridae/ Hantaviruses	Black Creek Canal	✸	2/3 implied (E)	C	3
Bunyaviridae/ Hantaviruses	El Moro Canyon	✸	2/3 implied (E)	C	3
Bunyaviridae/ Hantaviruses	Hantaan (Korean haemorrhagic fever)	✸	2/3 (E)	C	3
Bunyaviridae/ Hantaviruses	Hantaviruses (others known)	✸	2/3* (E)	C	3
Bunyaviridae/ Hantaviruses	Prospect Hill virus	✸	2/3 implied (E)	C	3
Bunyaviridae/ Hantaviruses	Puumala virus	✸	2/3 (E)	C	3
Bunyaviridae/ Hantaviruses	Seoul virus	✸	2/3 (E)	C	3
Bunyaviridae/ Hantaviruses	Sin nombre virus	✸	2/3 (E)	C	3
Bunyaviridae/ Nairovirus	Nairobi Sheep Disease		3 (I), R		BMBL
Bunyaviridae/ Nairoviruses	Congo Crimean haemorrhagic fever (Tick-borne encephalitis virus)	✸	4 (E)	C	4
Bunyaviridae/ Nairoviruses	Hazara virus		2		BMBL
Bunyaviridae/ Phleboviruses	Rift Valley Fever	✸	V2 (E), 3 (I/E)		V2, 3
Bunyaviridae/ Phleboviruses	Sandfly fever virus		2		BMBL
Bunyaviridae/ Phleboviruses	Toscana virus		2		BMBL
Bunyaviridae/ Phleboviruses	Zinga (See Rift Valley Fever)		V2 (E), 3 (E)		
Calciviridae	Calciviridae (others known)				2
Calciviridae	Hepatitis E virus		2		2
Calciviridae	Norwalk virus				2
Coronaviridae	Coronavirus				2
Filoviridae	Ebola virus	✸	4 (E)	A	4
Filoviridae	Marburg virus	✸	4 (E)	A	4
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Absettarov (Tick-borne encephalitis virus)	✸	3/4 (E)	C	4
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Central European Tick-borne encephalitis virus	✸	4 (E)	C	4
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Dengue virus		2		2

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Table A-2. Viral Microorganisms and Their Safety Classifications

Viral Group[1]	Name[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Hanzalova (Tick-borne encephalitis virus)	✸	3/4 (E)	C	4
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Hypr (Tick-borne encephalitis virus)	✸	3/4 (E)	C	4
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Kokobera		2		BMBL
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Kumlinge (Tick-borne encephalitis virus)	✸	3/4 (E)	C	4
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Kunjin		2		BMBL
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Kyasanur Forest (Tick-borne encephalitis virus)	✸	4 (E)	C	4
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Looping ill (Tick-borne encephalitis virus)	✸	3 (I)	C	BMBL
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Murray Valley encephalitis (Australian encephalitis)		3		BMBL
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Omsk (hemorrhagic fever), (Tick-borne encephalitis virus)	✸	4 (E)	C	4
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Powassan		3		BMBL
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Rocio		3		BMBL
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Russian spring-summer encephalitis (Tick-borne encephalitis virus)	✸	4 (E)	C	4
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Sammarez Reef		3		BMBL
Flaviviridae/ Flavivirus (Grp B Arbovirus)	St. Louis encephalitis		3		3
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Tick-borne	✸		C	BMBL
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Wesselsbron virus		3 (I)		BMBL
Flaviviridae/ Flavivirus (Grp B Arbovirus)	West Nile fever virus		3 (E)		BMBL
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Yellow fever virus (vaccine strain 17D)		V2 (E)		2
Flaviviridae/ Flavivirus (Grp B Arbovirus)	Yellow fever virus (wild type)	✸	3 (E)	C	3
Flaviviridae/Flavivirus (Grp B Arbovirus)	Japanese B encephalitis		3 (E)		3
Flaviviridae/Flavivirus (Grp B Arbovirus)	Japanese encephalitis, Nakayama		3 (E)		BMBL
Flavivirus	Flaviviruses (others known to be pathogenic)				BMBL
Hepadnaviridae	Hepatitis B virus		2		2
Hepadnaviridae	Hepatitis D (Delta) virus (b)		2		2
Herpesviridae	Herpesviruses (unassigned, HHV 7, HHV8)		2 implied		BMBL
Herpesviridae	Human B lympho-tropic virus				2 (types 6 and 7)
Herpesviridae	Rhadinovirus (except H.ateles,H. saimiri)				
Herpesviridae / Gamma-herpesvirinae	Gammaherpes				
Herpesviridae/ Alphaherpesviridae	Pseudorabies virus				
Herpesviridae/ Alpha-herpesviridae	Herpes simplex viruses		2		2 (types 1 and 2)
Herpesviridae/ Alpha-herpesviridae	Herpesvirus simiae (B virus)		2/3/4		4
Herpesviridae/ Alpha-herpesviridae	Herpesvirus zoster (Varicella)		2		2
Herpesviridae/ Animal virus vector	Herpesvirus saimiri (Genus Rhadinovirus)		2 implied		1
Herpesviridae/ Animal virus vector	Marek's disease virus				1
Herpesviridae/ Animal virus vector	Murine cytomegalovirus				1
Herpesviridae/ Animal virus vector	Thetalymphocryptovirus				

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Herpesviridae/ Betaherpesviridae	Cytomegalovirus (CMV) (Genus Lymphocryptovirus)		2		2
Herpesviridae/ Gamma-herpesviridae	Epstein-Barr virus (EBV)		2		2
Herpesviridae/ Rhadinovirus	Herpes saimiri				1
Herpesviridae/ Rhadinovirus	Herpesvirus ateles				1
Herpesviridae/ Rhadinovirus	Rhadinovirus (except H. ateles and H. saimiri)				BMBL
Orthomyxoviridae	Influenza virus (Types A-C)		2 (I)		2
Orthomyxoviridae	Influenza virus (vaccine strain)		1		BMBL
Orthomyxoviridae	Orthomyxoviridae (Tick-borne encephalitis virus)	✸	4	C	BMBL
Orthopoxvirus	Ectromelia (mousepox)				
Papovaviridae	Papillomaviruses (human)				2
Papovaviridae	Polyomavirus (BK and JC viruses)				1
Papovaviridae/ Animal virus vector	Simian virus 40 (SV40)				1
Papovavirus/ Animal virus vector	Shope papilloma virus				1
Papovavirus/Animal virus vector	Bovine papilloma virus				1
Paramyxoviridae	Subsclerosing pancencephalitis				
Paramyxoviridae/ Morbillivirus	Hendra and Hendra-like viruses		3+/4 (I/E)		4
Paramyxoviridae/ Morbillivirus	Measles virus				2
Paramyxoviridae/ Morbillivirus	Morbillivirus (except Rinderpest)				
Paramyxoviridae/ Paramyxovirus	Mumps virus				2
Paramyxoviridae/ Paramyxovirus	Newcastle Disease virus				2
Paramyxoviridae/ Paramyxovirus	Parainfluenza virus (Type 3, SF4 strain)				
Paramyxoviridae/ Paramyxovirus	Parainfluenza viruses				2 (Types 1-4)
Paramyxoviridae/ Pneumovirus	Respiratory syncytial virus				2
Paramyxoviruses/ Parainfluenza viruses	Sendai virus (murine parainfluenza virus type 1)				
Parvoviridae	Parvovirus (human)				2 (B19)
Picornaviridae	Acute haemorrhagic conjunctivitis virus (AHC)				
Picornaviridae	Aphthovirus				
Picornaviridae	Cardiovirus				
Picornaviridae/ Rhinoviruses	Rhinovirus				2
Picornoviridae/ Enterovirus	Coxsackie				2 (Types A and B)
Picornoviridae/ Enterovirus	Echoviruses				2
Picornoviridae/ Enterovirus	Entero				
Picornoviridae/ Enterovirus	Polioviruses		2/3		2
Picornoviridae/ Hepatovirus	Hepatitis A virus (human enterovirus type 72)		2		2
Poxviridae	Alastrim		2 implied (E)		R
Poxviridae	Buffalopox virus: 2 viruses (1a vaccinia variant)		2 implied (E)		2
Poxviridae	Camel pox virus		2 implied (E)		2
Poxviridae	Cowpox virus		2 (E)		2
Poxviridae	Elephantpox virus (variant of cowpox)		2 (E)		2
Poxviridae	Milker's node virus		2 implied (E)		2

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Poxviridae	Molluscum contagiosum virus		2 implied (E)		2
Poxviridae	Paravaccinia virus		2 implied (E)		2
Poxviridae	Rabbitpox virus (vaccinia variant)		2 (E)		2
Poxviridae	Tanapox		2 (E)		2
Poxviridae	Variola (major and minor) virus	✸	R	A	R
Poxviridae	Whitepox (Variola)		R	A	R
Poxviridae	Yabapox virus (Tana and Yaba)		2 (E)		
Poxviridae/ Orthopoxvirus	Monkeypox virus		2 (E)		3
Poxviridae/ Orthopoxvirus	Orthopoxviruses (other pathogenic, not in RG 2 or 4)		2 implied (E)		2
Poxviridae/ Orthopoxvirus	Vaccinia virus		2 (E)		2
Poxviridae/ Parapoxvirus	Orf virus		2 implied		2
Reoviridae	Coltiviruses				2 (incl. Colorado Tick Fever)
Reoviridae	Orbiviruses				2
Reoviridae	Reoviruses				2
Reoviridae	Rotavirus (human)				2
Retroviridae	Lentivirinae (except HIV-1 and HI)		2/3* implied		
Retroviridae	Simian sarcoma virus (SSV-1)		2/3* implied		
Retroviridae/ Lentiviridae	Human Immunodeficiency virus (HIV Types 1 and 2, Oncornavirus C)		2/3*		3 (Types 1 and 2)
Retroviridae/ Lentiviridae	Simian immunodeficiency virus		2/3*		3
Retroviridae/ Oncovirinae	Oncornavirus B		2/3* implied		
Retroviridae/ Oncovirinae	Oncornavirus C (except HTLV I and II)		2/3* implied		
Retroviridae/ Oncovirinae/ Genus Oncornavirus C	Human T-cell lymphotropic viruses (HTLV)		2/3* implied		3 (Types 1 and 2)
Rhabdoviridae	Flanders-Hart Park virus (see Zinsser, pg 777)		2		BMBL
Rhabdoviridae	Hart Park virus (see Zinsser, pg 777)		2		BMBL
Rhabdoviridae	Vesicular stomatitis virus		2/3 (I/E) some R		2 (lab adapted strains), 3
Rhabdoviridae/ Lyssavirus	Rabies virus		2 /3*		2
Togaviridae/ Alphavirus (Grp A Arbovirus)	Alphaviruses (others known)				
Togaviridae/ Alphavirus (Grp A Arbovirus)	Barmah Forest		2		BMBL
Togaviridae/ Alphavirus (Grp A Arbovirus)	Bebaru virus		2		BMBL
Togaviridae/ Alphavirus (Grp A Arbovirus)	Chikungunya virus		V2 (E), 3 (E)		BMBL
Togaviridae/ Alphavirus (Grp A Arbovirus)	Eastern equine encephalomyelitis (EEE)	✸	2 (I)	B	2
Togaviridae/ Alphavirus (Grp A Arbovirus)	Everglade virus		3		BMBL
Togaviridae/ Alphavirus (Grp A Arbovirus)	Mayaro virus		3		BMBL
Togaviridae/ Alphavirus (Grp A Arbovirus)	Mucambo virus		3		BMBL
Togaviridae/ Alphavirus (Grp A Arbovirus)	Ndumu		3		BMBL
Togaviridae/ Alphavirus (Grp A Arbovirus)	O'Nyong-Nyong virus		2		BMBL
Togaviridae/ Alphavirus (Grp A Arbovirus)	Ross River virus		2		BMBL
Togaviridae/ Alphavirus (Grp A Arbovirus)	Semliki Forest virus		3		3
Togaviridae/ Alphavirus (Grp A Arbovirus)	Sindbis virus		2		BMBL

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Viral Group[1]	Name[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
Togaviridae/ Alphavirus (Grp A Arbovirus)	Tonate virus		3/4 (E), some R		BMBL
Togaviridae/ Alphavirus (Grp A Arbovirus)	Venezuelan equine encephalomyelitis		V2 (E), 3 (I/E)	B	V2, 3
Togaviridae/ Alphavirus (Grp A Arbovirus)	Western equine encephalomyelitis		2 (I)	B	2
Togaviridae/ Pestivirus (Canada)	Hepatitis C		2		2
Togaviridae/ Rubivirus	Rubivirus (Rubella)				2
Toroviridae	Toroviridae				
Unclassified viruses	Hepatitis (bloodborne viruses not yet identified)		2 implied		2 implied
Unconventional agents, prions	Bovine spongiform encephalopathy (BSE)		2* (I)		
Unconventional agents, prions	Chronic wasting disease (CWD)		2		
Unconventional agents, prions	Creutzfeldt-Jacob disese		3		3
Unconventional agents, prions	Exotic ungulate encephalopathy (EUE)		2		
Unconventional agents, prions	Feline spongiform encephalopathy (FSE)		2		
Unconventional agents, prions	Gatal familial insomnia (FFI)		3		
Unconventional agents, prions	Gerstmann-Straussler-Scheinker syndrome		3*		3 implied
Unconventional agents, prions	Kuru		3*		3
Unconventional agents, prions	Scrapie		2* implied		
Unconventional agents, prions	Transmissible mink encephalopathy (TME)		2		
Viral vector/Animal retrovirus	Avian leukosis virus (ALV)				1
Viral vector/Animal retrovirus	Avian sarcoma virus				1
Viral vector/Animal retrovirus	Bovine immunodeficiency virus (BIV)				
Viral vector/Animal retrovirus	Bovine leukemia virus (BLV)				1
Viral vector/Animal retrovirus	Feline leukemia virus (FeLV)				1
Viral vector/Animal retrovirus	Feline sarcoma virus (FeSV)				1
Viral vector/Animal retrovirus	Gibbon leukemia virus (GaLV)				1
Viral vector/Animal retrovirus	Mason-Pfizer monkey virus				1
Viral vector/Animal retrovirus	Mouse mammary tumor virus				1
Viral vector/Animal retrovirus	Murine leukemia virus				1
Viral vector/Animal retrovirus	Murine sarcoma virus				1
Viral vector/Animal retrovirus	Rat leukemia virus				1
Viral vector/Animal virus	Baculovirus				
Viral vector/Animal virus	Chick embryo lethal orphan (CELO)				
Viral vector/Animal virus	Dog sarcoma				
Viral vector/Animal virus	Guinea pig herpes				
Viral vector/Animal virus	Hamster leukemia				
Viral vector/Animal virus	Lucke (frog) virus				
X-Arboviruses	Aino		3		BMBL
X-Arboviruses	Akabane		3		BMBL
X-Arboviruses	Araguari		3		BMBL
X-Arboviruses	Batama		2		BMBL
X-Arboviruses	Batken		3		BMBL
X-Arboviruses	Bhanja		3		BMBL
X-Arboviruses	Bimbo		3		BMBL
X-Arboviruses	Bluetongue		2 (E)		BMBL
X-Arboviruses	Bobaya		3		BMBL

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X-Arboviruses	Bobia		3		BMBL
X-Arboviruses	Buenaventura		3		BMBL
X-Arboviruses	Cabassou		3		BMBL
X-Arboviruses	Cache valley		2		BMBL
X-Arboviruses	Chim		3		BMBL
X-Arboviruses	Cocal		3		BMBL
X-Arboviruses	Dhori		3		BMBL
X-Arboviruses	Dugbe		3		BMBL
X-Arboviruses	Ganjam (E permit)				
X-Arboviruses	Garba		3		BMBL
X-Arboviruses	Germiston		3		BMBL
X-Arboviruses	Getah		3		BMBL
X-Arboviruses	Gordil		3		BMBL
X-Arboviruses	Guaratuba		2		BMBL
X-Arboviruses	Ibaraki		3		BMBL
X-Arboviruses	Inhangapi		3		BMBL
X-Arboviruses	Inini		3		BMBL
X-Arboviruses	Israel Turkey Mening.		3		BMBL
X-Arboviruses	Issyk-Kul		3		BMBL
X-Arboviruses	Itaituba		3		BMBL
X-Arboviruses	Kairi		3		BMBL
X-Arboviruses	Khasan		3		BMBL
X-Arboviruses	Koutango		3		BMBL
X-Arboviruses	Kyzylagach		3		BMBL
X-Arboviruses	LaCrosse virus		2		BMBL
X-Arboviruses	Langat virus		2		BMBL
X-Arboviruses	Middelburg		3		BMBL
X-Arboviruses	Nariva, Negishi		3		BMBL
X-Arboviruses	New Minto		3		BMBL
X-Arboviruses	Nodamura		3		BMBL
X-Arboviruses	Northway		3		BMBL
X-Arboviruses	Ouango		3		BMBL
X-Arboviruses	Oubangui		3		BMBL
X-Arboviruses	Paramushir		3		BMBL
X-Arboviruses	Piry		3 (I)		BMBL
X-Arboviruses	Razdan		3		BMBL
X-Arboviruses	Rochambeau		3		BMBL
X-Arboviruses	Sagiyama		3		BMBL
X-Arboviruses	Salanga		3		BMBL
X-Arboviruses	Santa Rosa		3		BMBL
X-Arboviruses	Saumarex Reef		3		BMBL
X-Arboviruses	Sepik		3		BMBL
X-Arboviruses	Slovakia		3		BMBL
X-Arboviruses	Spondweni		3		BMBL
X-Arboviruses	Tamdy		3		BMBL
X-Arboviruses	Telok Forest		3		BMBL
X-Arboviruses	Tlacotalpan		3		BMBL
X-Arboviruses	Tocio				BMBL
X-Arboviruses	Turlock virus		2		BMBL
	Nipah virus			C	
	Hemorrhagic fever agents and viruses undefined				4

[1] Basic name and viral group list is from ABSA 1998 with some additions.
[2] Select agent list is from 42 CFR 72
[3] Biosafety Level is from CDC 1999 - all organisms shown require import or transfer permit from CDC
[4] Risk Grouping from CDC 2000a
[5] NIH Risk Groups (RG) are from NIH 2001
RG 1 not associated with disease in healthy human adults
RG 2 associated with human disease that is rarely serious and prophylactic intervention ***often*** available
RG 3 associated with human disease that is serious or lethal and prophylactic intervention ***may be*** available
RG 4 associated with human disease that is serious or lethal and prophylactic intervention ***not usually*** available
E -- Requires export permit from CDC and/or Department of Commerce or USDA
I -- Requires import permit from CDC and/or Department of Commerce or USDA
R -- is for restricted authorization to use either by the CDC or USDA
V -- is for vaccine
* activities with high droplet or aerosol production potential

Table A-3. Fungi and their Safety Classifications

Genus[1]	Species[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
Absidia	*corymbifera*				
Absidia	*ramosa*				
Ajellomyces	*capsulatus*				
Ajellomyces	*dermatitidis*				
Aspergillus	*flavus*				
Aspergillus	*fumigatus*				
Aspergillus	*spp*				
Blastomyces	*dermatitidis*		2		2
Candida	*albicans*				
Candida	*spp*				
Cladosporium	*bantianum*		2		2
Cladosporium	*carrionii*				
Cladosporium	*trichoides*		2		2 (Xylo-hypha)
Cladophialopora	*bantians*		2		
Coccidioides	*immitis*		2, 3 arthro-conidia; cont. soil		3 (soil, sporul. cultures)
Cryptococcus	*neoformans*		2		2
Dactylaria	*gallopava*		2		2 (Ochro-conis)
Dermatophilus	*congolensis*				
Emmonsia	*parva*				
Epidermophyton	*floccosum*		2, implied		2, implied
Epidermophyton	*spp*		2		2
Exophiala	*dermatitidis*		2 (Wan-giella)		2 (Wan-giella)
Filobasidiella	*bacillispora*				
Filobasidiella	*neoformans*				
Fonsecaea	*compacta*				
Fonsecaea	*pedrosoi*		2		2
Geotrichum	*spp*				
Histoplasma	*capsulatum*		3 (capsulatum)		3 (capsulatum and duboisii)
Histoplasma	*farcinimosum*				
Histoplasma	*spp.*				
Loboa	*lobai*				
Madurella	*grisea*				
Madurella	*mycetomatis*				
Microsporum	*spp*		2		2
Mucor	*spp*				
Neotestudina	*rosatii*				

[1] Basic genus and specie list is from ABSA 1998 with some additions.

[2] Select agent list is from 42 CFR 72

[3] Biosafety Level is from CDC 1999 - all organisms shown require import or transfer permit from CDC

[4] Risk Grouping from CDC 2000a

[5] NIH Risk Groups (RG) are from NIH 2001
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RG 4 associated with human disease that is serious or lethal and prophylactic intervention not usually available

Table A-3. Fungi and their Safety Classifications

Genus[1]	Species[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
Ochroconis	*gallopavum*		2		
Paracoccidioides	*brasiliensis*				2
Penicillium	*marneffei*		2		2
Phialophora	*compacta*				
Phialophora	*pedrosoi*				
Ramichlorisium	*mackenzieim*		2		
Rhinocladiella	*compacta*				
Rhinocladiella	*pedrosoi*				
Rhizopus	*cohnii*				
Rhizopus	*microspous*				
Sporothrix	*schenckii*		2		2
Stachybotrus	*atra*		2		
Trichophyton	*rubrum*		2, implied		2, implied
Trichophyton	*spp*		2		2
Trichosporon	*spp*				
Xylohypha	*bantania*				
Zymonema	*dermatitidis*				

[1] Basic genus and specie list is from ABSA 1998 with some additions.

[2] Select agent list is from 42 CFR 72

[3] Biosafety Level is from CDC 1999 - all organisms shown require import or transfer permit from CDC

[4] Risk Grouping from CDC 2000a

[5] NIH Risk Groups (RG) are from NIH 2001
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Table A-4. Parasites and Their Safety Classification

Genus[1]	Species[1]	Group[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
Acanthamoeba	*castellani*	Protozoa		2		
Acanthamoeba	*spp*	Protozoa		2		
Acanthocheilonema	*spp*	Helminth, Nematode				
Ancylostoma	*duodenale*	Helminth, Nematode		2 implied		2
Ancylostoma	*spp*	Helminth, Nematode		2 implied		2
Ancylstoma	*ceylanicum*	Helminth, Nematode		2 implied		2
Angiostrongylus	*cantonensis*	Helminth, Nematode				
Angiostrongylus	*costaricensis*	Helminth, Nematode				
Angiostrongylus	*spp*	Helminth, Nematode				
Ascaris	*lumbricoides*	Helminth, Nematode		2 implied		2
Ascaris	*spp*	Helminth, Nematode		2		2
Ascaris	*suum*	Helminth, Nematode		2 implied		2
Babesia	*divergens*	Protozoa		2 implied		2
Babesia	*microti*	Protozoa		2 implied		2
Babesia	*spp*	Protozoa		2		2
Balamuthia	*spp.*	Protozoa		2		
Balantidium	*coli*	Protozoa				
Balantidium	*spp*	Protozoa				
Brugia	*malayi*	Helminth, Nematode		2 implied		2
Brugia	*pahangi*	Helminth, Nematode		2 implied		2
Brugia	*spp*	Helminth, Nematode		2 implied		2
Brugia	*timori*	Helminth, Nematode				2
Capillaria	*philippinensis*	Helminth, Nematode				

[1] Basic genus and specie list is from ABSA 1998 with some additions.

[2] Select agent list is from 42 CFR 72

[3] Biosafety Level is from CDC 1999 - all organisms shown require import or transfer permit from CDC

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Table A-4. Parasites and Their Safety Classification

Genus[1]	Species[1]	Group[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
Capillaria	*spp*	Helminth, Nematode				
Clonorchis	*sinensis*	Helminth, Trematode				
Clonorchis	*spp*	Helminth, Trematode				
Clonorchis	*viverrini*	Helminth, Trematode				
Coccidia	*spp*	Protozoa		2		2
Cyclospora	*cayetanensis*					
Cryptosporidium	*parvum*	Protozoa		2 implied		2
Cryptosporidium	*spp*	Protozoa		2		2
Cysticercus	*cellulosae*	Helminth, Cestode larva		2		2
Cysticercus	*spp*	Helminth, Cestode		2		2
Dicrocoelium	*spp*	Helminths, Trematode				
Dipetalonema	*perstans*	Helminth, Nematode				
Dipetalonema	*spp*	Helminth, Nematode				
Dipetalonema	*streptocerca*	Helminth, Nematode				
Diphyllobothrium	*latum*	Helminth, Cestode				
Diphyllobothrium	*spp*	Helminth, Cestode				
Dipylidium	*spp*	Helminth, Cestoda				
Dracunculus	*medinensis*	Helminth, Nematode				
Dracunculus	*spp*	Helminth, Nematode				
Echinococcus	*granulosis*	Helminth, Cestode		2 implied		2
Echinococcus	*multilocularis*	Helminth, Cestode		2 implied		2

[1] Basic genus and specie list is from ABSA 1998 with some additions.

[2] Select agent list is from 42 CFR 72

[3] Biosafety Level is from CDC 1999 - all organisms shown require import or transfer permit from CDC

[4] Risk Grouping from CDC 2000a

[5] NIH Risk Groups (RG) are from NIH 2001
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Table A-4. Parasites and Their Safety Classification

Genus[1]	Species[1]	Group[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
Echinococcus	*spp*	Helminth, Cestode		2		2
Echinococcus	*vogeli*	Helminth, Cestode		2 implied		2
Entamoeba	*histolytica*	Protozoa		2		2
Enterobius	*spp*	Helminth, Nematode		2		2
Fasciola	*gigantica*	Helminth, Trematode		2 implied		2
Fasciola	*Hepatica*	Helminth, Trematode		2 implied		2
Fasciola	*spp*	Helminth, Trematode		2 (metacercariae)		2
Fasciolopsis	*buski*	Helminth, Trematode				
Fasciolopsis	*spp*	Helminth, Trematode				
Giardia	*lamblia*	Protozoa		2 implied		2
Giardia	*spp*	Protozoa		2		2
Hartmanella	*spp*	Protozoa				
Heterophyes	*spp*	Helminth, Trematode		2		2
Hymenolepis	*diminuta*	Helminth, Cestode				2
Hymenolepis	*nana*	Helminth, Cestode		2		2
Hymenolepis	*spp*	Helminth, Cestode		2		2
Isospora	*spp*	Protozoa		2 implied, Coccidia		2
Leishmania	*braziliensis*	Protozoa		2 implied		2
Leishmania	*donovani*	Protozoa		2 implied		2
Leishmania	*ethiopica*	Protozoa		2 implied		2
Leishmania	*major*	Protozoa		2 implied		2
Leishmania	*mexicana*	Protozoa		2 implied		2
Leishmania	*peruviania*	Protozoa		2 implied		2
Leishmania	*spp.*	Protozoa		2		2
Leishmania	*tropica*	Protozoa		2 implied		2

[1] Basic genus and specie list is from ABSA 1998 with some additions.

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[4] Risk Grouping from CDC 2000a

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Table A-4. Parasites and Their Safety Classification

Genus[1]	Species[1]	Group[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
Linguatula	*spp*	Arthropod				
Loa	*loa*	Helminth, Nematode		2 implied		2
Loa	*spp*	Helminth, Nematode		2 implied		2
Macracanthorhynchus	*spp*	Acanthocephala				
Mansonella	*ozzardi*	Helminth, Nematode				
Mansonella	*perstans*	Helminth, Nematode				
Microsporidium	*spp.*	Protozoa		2 implied		2
Naegleria	*fowleri*	Protozoa		2		2
Naegleria	*gruberi*	Protozoa		1		1
Naegleria	*spp*	Protozoa		2		1 or 2
Necator	*americanus*	Helminth, Nematode		2		2
Necator	*spp*	Helminth, Nematode		2		2
Onchocerca	*spp*	Helminth, Nematode		2 implied		2
Onchocerca	*volvulus*	Helminth, Nematode		2 implied		2
Opisthorchis	*felineus*	Helminth, Trematode				
Opisthorchis	*spp*	Helminth, Trematode				
Paragonimus	*spp*	Helminth, Trematode				
Paragonimus	*westermanii*	Helminth, Trematode				
Piroplasma	*spp*	Protozoa				
Plasmodium	*cynomologi*	Protozoa		2		2
Plasmodium	*falciparum*	Protozoa		2 implied		2
Plasmodium	*malariae*	Protozoa		2 implied		2
Plasmodium	*ovale*	PRotozoa		2 implied		2
Plasmodium	*simian parasites*	Protozoa		2 implied		2
Plasmodium	*spp*	Protozoa		2		2

[1] Basic genus and specie list is from ABSA 1998 with some additions.

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Table A-4. Parasites and Their Safety Classification

Genus[1]	Species[1]	Group[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
Plasmodium	*vivax*	Protozoa		2 implied		2
Pneumocystis	*carinii*	Protozoa				
Sarcocystis	*spp*	Protozoa		2		2
Sarcocystis	*sui hominis*	Helminth, Cestode larva		2 implied		
Schistosoma	*haematobium*	Helminth, Trematode		2 implied		2
Schistosoma	*intercalatum*	Helminth, Trematode		2 implied		2
Schistosoma	*japonicum*	Helminth, Trematode		2 implied		2
Schistosoma	*mansoni*	Helminth, Trematode		2 implied		2
Schistosoma	*mekongi*	Helminth, Trematode		2 implied		2
Schistosoma	*spp*	Helminth, Trematode		2		2
Strongyloides	*spp*	Helminth, Nematode		2		2
Strongyloides	*stercoralis*	Helminth, Nematode		2 implied		2
Taenia	*saginata*	Helminth, Cestode				
Taenia	*solium*	Helminth, Cestode		2		2
Taenia	*spp*	Helminth, Cestode				2
Toxascaris	*spp*	Helminth, Nematode				
Toxocara	*canis*	Helminth, Nematode				2
Toxocara	*spp*	Helminth, Nematode				2
Toxoplasma	*gondii*	Protozoa		2 implied		2
Toxoplasma	*spp*	Protozoa		2		2
Trichinella	*spiralis*	Helminth, Nematode				2
Trichomonas	*vaginalis*	Protozoa				

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Table A-4. Parasites and Their Safety Classification

Genus[1]	Species[1]	Group[1]	Select Agents[2]	CDC Biosafety Level[3]	CDC Risk Group[4]	NIH Risk Group[5]
Trichostrongylus	*spp*	Helminth, Nematode				
Trichuris	*trichiura*	Helminth, Nematode				
Trypanosoma	*brucei brucei*	Protozoa		2 implied		2
Trypanosoma	*brucei gambiense*	Protozoa		2 implied		2
Trypanosoma	*brucei rhodensiense*	Protozoa		2 implied		2
Trypanosoma	*cruzi*	Protozoa		2 implied		2
Trypanosoma	*spp*	Protozoa		2		2
Wuchereria	*bancroftii*	Helminth, Nematode		2 implied		2
Wuchereria	*spp*	Helminth, Nematode		2		2

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[3] Biosafety Level is from CDC 1999 - all organisms shown require import or transfer permit from CDC

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